PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Li Wang	Examiner:	Alyssa M. Alter
Serial No.:	10/684,759	Group Art Unit:	3762
Filed:	14 October 2003	Docket:	P0011118.00
		Conf. No.:	3360

Title: METHOD AND APPARATUS FOR MONITORING TISSUE FLUID CONTENT FOR USE IN AN IMPLANTABLE CARDIACE DEVICE

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The following Brief is submitted pursuant to the Notice of Appeal mailed June 29, 2009.

Any required fee will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.16, 1.17, 1.136(a), or any additional fees to Deposit Account 13-2546.

I. Real party in interest

The real party in interest in this application is Medtronic, Inc, assignee of the application.

II. Related appeals and interferences

None

III. Status of the claims

Claims 72 – 106 are believed to be pending. All claims stand rejected. The rejections of claims 80 - 81, 82 (first occurrence) 83 – 86 and 95 – 102 are hereby appealed.

IV. Status of amendments

The Amendment mailed March 30, 2009 is apparently un-entered. Applicants received no advisory action following submission of the amendment.

By means of the amendment of March 30, it was proposed that claims 72 – 79, 82 (the second), 87 – 94 and 103 -106 were to be cancelled. Claims 80, 83, 85, 95, 98, 99, and 101 were to be rewritten as independent claims but otherwise left unchanged. Claims 81, 82 (the first), 84, 86, 96, 97, 100, and 102 were to remain as previously submitted.

The Claims Appendix contains clean copies of the claims both as proposed to be amended and without amendment.

The claims appealed are identical in scope in both their amended and un-amended versions.

V. Summary of claimed subject matter

The claims on appeal include claims 80, 83, 85, 95, 98, 99 and 101 and claims dependent thereon. These claims were intended to be amended to take the form of independent claims by means of the un-entered amendment of March 30, 2009.

CLAIM 80

Claim 80 sets forth a method for monitoring intra-thoracic fluid content using an implanted cardiac stimulation device comprising at least two implanted electrodes. Examples of the electrodes and the stimulation device are illustrated in Figure 1 and generally described in paragraphs [0035 – 41].

Responsive to occurrence of a cardiac event, an impedance measurement pulse is delivered at a predetermined interval therefrom. This step is illustrated in Figure 10 at 505 and is described generally in paragraphs [0113 – 14] and is described in more detail in paragraphs [0058- 59]

Impedance between the two electrodes is then measured using the delivered impedance measurement pulse. This step is described generally in paragraphs [0061-62].

The first three (should be corrected to two) steps are performed repeatedly over a period extending over multiple days to acquire a set of impedance data. This process is illustrated generally in Figure 10 and is described generally in paragraphs [0117 – 118] and more specifically in paragraph [0063]. The extension of the process over multiple days is described in paragraph [0094].

The set of impedance data is then employed to determine whether intra-thoracic fluid content is increasing or decreasing. This step is illustrated generally in Figure 10 at 545 and generally discussed in paragraph [0120]. The determination is discussed in more detail in paragraphs [0109 – 13] and [0051 – 52].

Finally, the device must comprise leads carrying the electrodes and the method further comprises employing the measured impedances to assess the integrity of the leads. The leads carrying the electrodes are also illustrated in Figure 1 and described in paragraphs [0036 – 41]. The use of the measured impedances to determine lead integrity is illustrated in Figure 11 and described generally in paragraph [0126]. This step is further illustrated in Figure 12 and is discussed in more detail in paragraphs [136 – 137].

CLAIM 83

Claim 83 sets a method for monitoring intra-thoracic fluid content using an implanted cardiac stimulation device comprising at least two implanted electrodes. The method comprises the first four steps as described above in conjunction with claim 80 with the added step of declaring the set of impedance data flawed is performed responsive to a measured impedance differing from a prior measured impedance by more than a defined amount. This step is part of the step illustrated in Figure 10 at 525 and is illustrated in more detail in Figure 12. If the impedance changes more than a defined amount from a previous measurement, as discussed in paragraph described in paragraphs [0130 – 37], the impedance data is declared flawed and discarded as illustrated in Figure 10 at 530.

CLAIM 85

Claim 85 sets forth a method for monitoring intra-thoracic fluid content using an implanted cardiac stimulation device comprising at least two implanted electrodes. The method comprises the first four steps as described above in conjunction with claim 80 with the added requirement that the device comprises at least a third electrode and the added step of performing a cross check of the measured impedance values by measuring an impedance using the third electrode. This step is illustrated in Figure 12 and is discussed in more detail in paragraphs [136 – 137].

CLAIM 95

Claim 95 sets forth an implantable device capable of measuring intra-thoracic fluid content. The device comprises at least two implantable electrodes. Examples of the electrodes and the stimulation device are illustrated in Figure 1 and generally described in paragraphs [0035 – 41].

The device comprises means for determining occurrences of cardiac events. these means include the sense amplifiers 200, as illustrated in Figure 2 and as described in paragraphs [0046 – 47].

The device further comprises an impedance measurement means for measuring impedance between the electrodes repeatedly over a period extending over multiple days to acquire a set of impedance data. The impedance measurement means comprises the fluid status monitor 260 as illustrated in Figure 2 and in more detail in Figure 5. The fluid status monitor is discussed in detail in paragraphs [0059 – 62] and [84 – 91].

means responsive to occurrence of a cardiac event, for delivering an impedance measurement pulse (pulse generator 348 Figure 5, paragraph [0087] separated by a predetermined interval therefrom (stored in FSM control register 342, paragraph [0087]).

The measurement means further comprises means for measuring impedance between the two electrodes using the delivered impedance measurement pulse (FSM control circuitry 320, Figure 5, paragraphs [0089 – 90]).

The measurement means further comprises means responsive to the set of impedance data for determining whether intra-thoracic fluid content is increasing or decreasing (microprocessor 224, memory 226, Figures 2 and 5, paragraphs [0049 – 52]. The process employed to make the determination is discussed in detail in paragraphs [0109-0113] as discussed above in conjunction with the method claims.

Fiinally, the device comprises leads carrying the electrodes and wherein the device further comprises means for employing the measured impedances to assess the integrity of the leads. The leads carrying the electrodes are also illustrated in Figure 1 and described in paragraphs [0036 – 41]. The processor 224 uses the measured impedances to determine lead integrity as illustrated in Figure 11 and described in paragraphs [0126 – 126]. The process employed is further illustrated in Figure 12 and is discussed in more detail in paragraphs [136 – 137].

CLAIM 98

Claim 98 sets forth an implantable device capable of measuring intra-thoracic fluid content, comprising the first six elements of claim 95, with the addition of means for declaring the set of impedance data valid responsive to a measured impedance differing from a prior measured impedance by less than a defined amount. This function is performed by th microprocessor 224 as discussed above. The process employed by the microprocessor is step illustrated generally in Figure 10 at 525 and is illustrated in

more detail in Figure 12. If the impedance changes less than a defined amount from a previous measurement, as discussed in paragraph described in paragraphs [0130 – 37], the impedance data is declared valid.

CLAIM 99

Claim 99 sets forth an implantable device capable of measuring intra-thoracic fluid content, comprising the first six elements of claim 95, with the addition of means for declaring the set of impedance data flawed responsive to a measured impedance differing from a prior measured impedance by more than a defined amount. This function is performed by the microprocessor 224 as discussed above. The process employed by the microprocessor is step illustrated generally in Figure 10 at 525 and is illustrated in more detail in Figure 12. If the impedance changes more than a defined amount from a previous measurement, as discussed in paragraph described in paragraphs [0130 – 37], the impedance data is declared flawed.

:

CLAIM 101

Claim 101 sets forth an implantable device capable of measuring intra-thoracic fluid content, comprising the first six elements of claim 95, with the addition of a third electrode, means for measuring an impedance employing the third electrode and means for performing a cross check of the set of impedance data by measuring an impedance using the third electrode. These functions are performed by the microprocessor 224, as discussed above. This process is illustrated in Figure 12 and is discussed in more detail in paragraphs [136 – 137].

Claims dependent on the above-discussed claims also include limitations as discussed above, supported by the same portions of the specification.

VI. Grounds of rejection to be reviewed on appeal – Rejection of claims 80 - 81, 82 (first occurrence) 83 – 86 and 95 – 102 over Combs, et al.

In the Final Office Action, claims 80 - 81, 82 (first occurrence) 83 – 86 and 95 – 102 were rejected as obvious over U.S Patent No. 6,512,949, issued to Combs, et al. This rejection is respectfully traversed.

VII. Argument - Rejection of claims 80 - 81, 82 (first occurrence) 83 – 86 and 95 – 102 over Combs, et al.

The arguments presented below are based upon the claims discussed above. Patentability of the claims dependent thereon is not separately argued.

Independent claims 72 and 87, from which all claims on appeal depend require synchronization of the impedance measurements so that they occur at predetermined intervals following cardiac events. Modifying Combs '949 to perform in this manner is contradictory to the teaching of the cited patent and would appear to prevent the device disclosed therein from functioning as intended.

In Combs, et al., the measurement of fluid content is accomplished by extracting measurements of impedance made using an ongoing series of biphasic pulses which are already underway more or less continuously to measure another physiologic parameter, i.e. respiration. The present invention instead need only trigger delivery of impedance measurement pulses responsive to cardiac events, e.g. ventricular pacing and sensing. Modifying the device of the Combs, et al. patent to operate as claimed in the claims on appeal is believed to be unobvious. Triggering delivery of impedance measurement pulses responsive to ventricular events and coupled thereto would be unnecessary if an ongoing series of biphasic impedance measurement pulses were

generally underway to sense respiration, as in Combs, et al. Turning off the ongoing series of biphasic pulses would be unobvious as it would defeat the purpose of measuring respiration as described in Combs, et al.

More importantly, all claims on appeal require the use of these impedances, measured at the defined intervals, to determine whether these impedance measurements are reliable. This determination is made by determining whether the leads over which they are measured are functioning properly (Claims 80 and 95); by comparing them to previous measurements (Claims 83, 98 and 99) or by cross checking with a third electrode (Claims 85 and 101). None of these features is disclosed in Combs '949.

Combs '949 deals with impedance measurements made under different circumstances than those claimed, for a different purpose. It is respectfully asserted that modifying the impedance measurement system of Comb's '949 to meet the timing requirements of the claims and then adding to the functions performed to the impedance measurements as presently claimed cannot be obvious over Combs '949, absent, given that the purposes of the impedance measurements are different from the outset. Basically, it is asserted that modifying an element of a reference to perform in a new way and then additionally modifying it to perform new functions related to the new way of operation cannot both be obvious over a single reference absent some teaching relevant to the new way of operation and/or the new functions. Withdrawal of the rejection of the remaining claims over Comb '949 is requested for this reason as well.

It is respectfully requested that any new ground of rejection be in the form of a non-final rejection, as no claims have been amended in a manner that would allow for a second final rejection based upon new references.

Conclusion

All remaining claims are believed unobvious over Combs '949. Contrary to Combs, which teaches measuring fluid content using a mechanism which already measures a related physiologic parameter (respiration), the invention as claimed is directed to using a mechanism previously used as a diagnostic for testing the physical operability of the implanted device itself. This approach, while inconsistent with accomplishing the desired capabilities of Combs '949 nonetheless provides advantages in the form of the ability to check the validity of the measured fluid content, a benefit unavailable in Combs '949 and unappreciated in and unsuggested by the disclosure of Combs '949.

All remaining claims are therefore believed to be allowable over the Combs '949 patent. Reconsideration of the rejections of the remaining claims is respectfully requested.

Finally, if there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned attorney to attend to these matters.

`The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

Date: August 31, 2009

/Reed A. Duthler/
Reed A. Duthler
Reg. No. 30,626
Telephone: (763) 526-1564
Customer No. 27581

VIII. Appendix - Claims on Appeal

Claims as they stand with the Amendment of March, 2009 un-entered.

Claims 1 – 71 (Cancelled)

72. A method for monitoring intra-thoracic fluid content using an implanted cardiac stimulation device comprising at least two implanted electrodes, the method comprising:

responsive to occurrence of a cardiac event, delivering an impedance measurement pulse at a predetermined interval therefrom;

measuring impedance between the two electrodes using the delivered impedance measurement pulse;

performing the first three steps repeatedly over a period extending over multiple days to acquire a set of impedance data;

employing the set of impedance data to determine whether intra-thoracic fluid content is increasing or decreasing.

73. The method of claim 72 wherein the stimulation device comprises a sense amplifier having a blanking period and wherein delivery of the impedance measurement pulse is performed during the blanking period.

74. The method of claim 72 wherein delivery of the impedance measurement pulse is performed by delivery of a monophasic pulse.

75. The method of claim 74 wherein the stimulation device comprises a sense amplifier having a blanking period and wherein delivery of the impedance measurement pulse is performed during the blanking period.

76. The method of claim 74, wherein delivery of the impedance measurement pulse is performed within 10 – 30 ms of the cardiac event.

77. The method of claim 72, wherein delivery of the impedance measurement pulse is performed 10 – 30 ms of the cardiac event.

78. The method of claim 72, further comprising providing an indication that intra-thoracic fluid content is increasing or decreasing.

79. The method of claim 72, further comprising filtering the set of impedance data to remove impedance changes due to respiration.

80. The method of claim 72, wherein the device comprises leads carrying the electrodes and wherein the method further comprises employing the measured impedances to assess the integrity of the leads.

81. The method of claim 80, further comprising declaring the set of impedance data flawed responsive to the assessment of the integrity of the leads.

82. The method of claim 81, wherein assessment of the integrity of the leads comprises comparing a measured impedance to a prior measured impedance to determine whether the measured impedance differs from the prior measured impedance by more than a defined amount.

82. The method of claim 81, further comprising declaring the set of impedance data valid responsive to the measured impedance differing from the prior measured impedance by less than the defined amount.

83. The method of claim 72, wherein declaring the set of impedance data flawed is performed responsive to a said measured impedance differing from a prior said measured impedance by more than a defined amount.

84. The method of claim 83, further comprising declaring the set of impedance data valid responsive to the said measured impedance differing from the said prior measured impedance by less than the defined amount.

85. The method of claim 72, wherein the device comprises at least a third electrode and wherein the method further comprises performing a cross check of the measured impedance values by measuring an impedance using the third electrode.

86. The method of claim 85, wherein the method further comprises declaring the set of impedance data flawed is performed responsive to the impedance measured using the third electrode.

87. A implantable device capable of measuring intra-thoracic fluid content, comprising:

at least two implantable electrodes,:

means for determining occurrences of cardiac events;

an impedance measurement means for measuring impedance between the electrodes repeatedly over a period extending over multiple days to acquire a set of impedance data, the impedance measurement means comprising:

means responsive to occurrence of a cardiac event, for delivering an impedance measurement pulse separated by a predetermined interval therefrom;

means for measuring impedance between the two electrodes using the delivered impedance measurement pulse; and

means responsive to the set of impedance data for determining whether intra-thoracic fluid content is increasing or decreasing.

88. The device of claim 87 wherein the stimulation device comprises a sense amplifier having a blanking period and wherein the means for delivering the impedance measurement pulse comprises means for delivering the impedance measurement pulse during the blanking period.

89. The device of claim 87 wherein the means for delivering the impedance measurement pulse comprises means for delivery of a monophasic pulse.

90. The device of claim 89 wherein the stimulation device comprises a sense amplifier having a blanking period and wherein the means for delivering the impedance measurement pulse comprises means for delivering the impedance measurement pulse during the blanking period.

91. The device of claim 89, wherein the means for delivering the impedance measurement pulse comprises means for delivering the impedance measurement pulse 10 – 30 ms of the cardiac event.

92. The device of claim 87, wherein the means for delivering the impedance measurement pulse comprises means for delivering the impedance measurement pulse 10 – 30 ms of the cardiac event.

93 The device of claim 87, further comprising means for providing an indication that intra-thoracic fluid content is increasing or decreasing.

94. The device of claim 87, further comprising means for filtering the set of impedance data to remove impedance changes due to respiration.

95. The device of claim 87, wherein the device comprises leads carrying the electrodes and wherein the device further comprises means for employing the measured impedances to assess the integrity of the leads.

96. The device of claim 95, further comprising means for declaring the set of impedance data flawed responsive to the assessment of the integrity of the leads.

97. The device of claim 96, wherein the means for assessment of the integrity of the leads comprises means for comparing a measured impedance to a prior measured impedance to determine whether the measured impedance differs from the prior measured impedance by more than a defined amount.

98. The method of claim 87, further comprising means for declaring the set of impedance data valid responsive to a measured impedance differing from a prior measured impedance by less than a defined amount.

99. The device of claim 87, further comprising means for declaring the set of impedance data flawed responsive to a measured impedance differing from a prior measured impedance by more than a defined amount.

100. The device of claim 99, further comprising means for declaring the set of impedance data valid responsive to a measured impedance differing from a prior measured impedance by less than the defined amount.

101. The device of claim 87 further comprising:
a third electrode;
means for measuring an impedance employing the third electrode and
means for performing a cross check of the set of impedance data by measuring an impedance using the third electrode.

102. The device of claim 101, further comprising:
means for declaring the set of impedance data flawed responsive to the impedance measured using the third electrode.

103. The device of claim 87, wherein the means for determining occurrences of cardiac events comprises means for sensing ventricular events.

104. The device of claim 87, wherein the means for determining occurrences of cardiac events comprises delivering ventricular pacing pulses.

105. The method of claim 72, wherein delivering an impedance measurement pulse is performed responsive to a sensed ventricular event.

106. The device of claim 72, wherein delivering an impedance measurement pulse is performed responsive to a paced ventricular event.

Claims as they would be with the Amendment of March, 2009 entered.

Claims 1 – 79 (Cancelled)

80. A method for monitoring intra-thoracic fluid content using an implanted cardiac stimulation device comprising at least two implanted electrodes, the method comprising:

responsive to occurrence of a cardiac event, delivering an impedance measurement pulse at a predetermined interval therefrom;

measuring impedance between the two electrodes using the delivered impedance measurement pulse;

performing the first three steps repeatedly over a period extending over multiple days to acquire a set of impedance data;

employing the set of impedance data to determine whether intra-thoracic fluid content is increasing or decreasing; and

wherein the device comprises leads carrying the electrodes and wherein the method further comprises employing the measured impedances to assess the integrity of the leads.

81. The method of claim 80, further comprising declaring the set of impedance data flawed responsive to the assessment of the integrity of the leads.

82. The method of claim 81, wherein assessment of the integrity of the leads comprises comparing a measured impedance to a prior measured impedance to determine whether the measured impedance differs from the prior measured impedance by more than a defined amount.

82. (Second occurrence, cancelled)

83. A method for monitoring intra-thoracic fluid content using an implanted cardiac stimulation device comprising at least two implanted electrodes, the method comprising:

responsive to occurrence of a cardiac event, delivering an impedance measurement pulse at a predetermined interval therefrom;

measuring impedance between the two electrodes using the delivered impedance measurement pulse;

performing the first three steps repeatedly over a period extending over multiple days to acquire a set of impedance data;

employing the set of impedance data to determine whether intra-thoracic fluid content is increasing or decreasing; and

herein declaring the set of impedance data flawed is performed responsive to a said measured impedance differing from a prior said measured impedance by more than a defined amount.

84. The method of claim 83, further comprising declaring the set of impedance data valid responsive to the said measured impedance differing from the said prior measured impedance by less than the defined amount.

85. A method for monitoring intra-thoracic fluid content using an implanted cardiac stimulation device comprising at least two implanted electrodes, the method comprising:

responsive to occurrence of a cardiac event, delivering an impedance measurement pulse at a predetermined interval therefrom;

measuring impedance between the two electrodes using the delivered impedance measurement pulse;

performing the first three steps repeatedly over a period extending over multiple days to acquire a set of impedance data;

employing the set of impedance data to determine whether intra-thoracic fluid content is increasing or decreasing; and

wherein the device comprises at least a third electrode and wherein the method further comprises performing a cross check of the measured impedance values by measuring an impedance using the third electrode.

86. The method of claim 85, wherein the method further comprises declaring the set of impedance data flawed is performed responsive to the impedance measured using the third electrode.

87 - 94. (Cancelled)

95. A implantable device capable of measuring intra-thoracic fluid content, comprising:

at least two implantable electrodes,:

means for determining occurrences of cardiac events;

an impedance measurement means for measuring impedance between the electrodes repeatedly over a period extending over multiple days to acquire a set of impedance data, the impedance measurement means comprising:

means responsive to occurrence of a cardiac event, for delivering an impedance measurement pulse separated by a predetermined interval therefrom;

means for measuring impedance between the two electrodes using the delivered impedance measurement pulse; and

means responsive to the set of impedance data for determining whether intra-thoracic fluid content is increasing or decreasing; and

wherein the device comprises leads carrying the electrodes and wherein the device further comprises means for employing the measured impedances to assess the integrity of the leads.

96. The device of claim 95, further comprising means for declaring the set of impedance data flawed responsive to the assessment of the integrity of the leads.

97. The device of claim 96, wherein the means for assessment of the integrity of the leads comprises means for comparing a measured impedance to a prior measured impedance to determine whether the measured impedance differs from the prior measured impedance by more than a defined amount.

98. A implantable device capable of measuring intra-thoracic fluid content, comprising:

at least two implantable electrodes,:

means for determining occurrences of cardiac events;

an impedance measurement means for measuring impedance between the electrodes repeatedly over a period extending over multiple days to acquire a set of impedance data, the impedance measurement means comprising:

means responsive to occurrence of a cardiac event, for delivering an impedance measurement pulse separated by a predetermined interval therefrom;

means for measuring impedance between the two electrodes using the delivered impedance measurement pulse; and

means responsive to the set of impedance data for determining whether intra-thoracic fluid content is increasing or decreasing; and

further comprising means for declaring the set of impedance data valid responsive to a measured impedance differing from a prior measured impedance by less than a defined amount.

99. A implantable device capable of measuring intra-thoracic fluid content, comprising:

at least two implantable electrodes,:

means for determining occurrences of cardiac events;

an impedance measurement means for measuring impedance between the electrodes repeatedly over a period extending over multiple days to acquire a set of impedance data, the impedance measurement means comprising:

means responsive to occurrence of a cardiac event, for delivering an impedance measurement pulse separated by a predetermined interval therefrom;

means for measuring impedance between the two electrodes using the delivered impedance measurement pulse; and

means responsive to the set of impedance data for determining whether intra-thoracic fluid content is increasing or decreasing; and

further comprising means for declaring the set of impedance data flawed responsive to a measured impedance differing from a prior measured impedance by more than a defined amount.

100. The device of claim 99, further comprising means for declaring the set of impedance data valid responsive to a measured impedance differing from a prior measured impedance by less than the defined amount.

101. A implantable device capable of measuring intra-thoracic fluid content, comprising:

at least two implantable electrodes,:

means for determining occurrences of cardiac events;

an impedance measurement means for measuring impedance between the electrodes repeatedly over a period extending over multiple days to acquire a set of impedance data, the impedance measurement means comprising:

means responsive to occurrence of a cardiac event, for delivering an impedance measurement pulse separated by a predetermined interval therefrom;

means for measuring impedance between the two electrodes using the delivered impedance measurement pulse; and

means responsive to the set of impedance data for determining whether intra-thoracic fluid content is increasing or decreasing; and further comprising:

a third electrode;

means for measuring an impedance employing the third electrode and

means for performing a cross check of the set of impedance data by measuring an impedance using the third electrode.

102. The device of claim 101, further comprising:

means for declaring the set of impedance data flawed responsive to the impedance measured using the third electrode.

103 - 106. (Cancelled)

IX Appendix – Evidence

None

X. Appendix – Other proceedings

None